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10/019,465

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Morten Bay Alexandersen

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07/27/2004

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EXAMINER

TRUONG, LINH T

ART UNIT

PAPER NUMBER

3761

7

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,465

Applicant(s)

ALEXANDERSEN ET AL.

Examiner

Linh Truong

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5 and 12-18 is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☒ Claim(s) 6-11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because of the word "said" in the first line. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: on p.9, lines 9-10 and for claim 4, in the fourth line, it is suggested that Applicant replace the phrase "a net material of **eg. metal**" with "a net material **that is metal**" for the sake of clarity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3761

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Coulter '5,417,666 (IDS).

For claims 1-2, 5, and 17, Coulter teaches a flexible (plastic or polyethylene film) access member that is hose-shaped with an outer end 6 and an inner end 8 with two walls and a cavity 10 extending therethrough for the insertion of a catheter (figs. 1-3). This access member is fully capable of being in a closed position due to its flexibility and to its inserted position in a natural canal (e.g. the urethra) that normally contracts.

For claim 3, Coulter teaches using petrolatum or petroleum jelly, both of which are considered gels, on the walls of the access member for lubrication (col. 5, lines 1-5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coulter '5,417,666 (IDS).

For claim 4, Coulter does not teach using a net material made from metal instead, Coulter teaches using flexible plastic, polyethylene, or similar materials. It would have been an obvious matter of design choice to have a net material made of

metal, since applicant has not disclosed that net material made of metal solves any stated problem, has any criticality, or is for any particular purpose and it appears that the invention would perform equally well with flexible plastic, polyethylene, or similar materials.

For claim 18, although Coulter does not expressly teach the method of replacing the access member by removing a first access member and then replacing it with another access member. It is obvious to one with ordinary skill in the art that urinary catheters, and therefore, urinary access members, have a certain lifespan (and they might be defective) and that they need to be replaced regularly to prevent infections and ensure performance. It is also obvious that in order to replace the access member, the first one has to be removed (either before or after) the insertion of a new one.

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coulter '5,417,666 (IDS) in view of Kalb et al. (Kalb) '5,704,353 (IDS).

For claim 12, Coulter does not teach that the inner end of the access member has a cap with multiple openings. It is well known in the art that catheters have multiple holes at their inner ends for draining fluids from body cavities. Kalb teaches a catheter with the same structure as the access member of Coulter wherein a stylet can be inserted therethrough with an inner end that has a cap 18 with multiple openings 20 (fig. 3). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the access member of Coulter with a cap that has multiple drainings for drainage of bodily fluids.

For claims 13-14, Coulter does not teach a plate for securing the access member to the abdominal skin surface. It is common in the art to make sure that the access member does not become inadvertently dislodged from the user. Kalb teaches an access member 10 (for the insertion of a stylet 30) with a plate 16 that adheres to the abdominal area (col. 3, lines 39-41). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the access member of Coulter with the plate of Kalb for a more secure fit.

For claim 15 Coulter and Kalb do not teach using an adhesive, Kalb, instead, teaches that the access member fitting properly in order for the plate to adhere securely to the abdominal area. It would have been an obvious matter of design choice to have adhesive material, since applicant has not disclosed that an adhesive solves any stated problem, has any criticality, or is for any particular purpose and it appears that the invention would perform equally well with an access member that fits properly.

For claim 16, Coulter does not teach a plug member inserted into the access member. Plugs are well known in the art to ensure against leakage. Kalb teaches a plug 80 (fig. 8 and col. 4, lines 26-30). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the access member of Coulter with a plug to ensure against leakage.

Allowable Subject Matter

Claims 6-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not teach or render obvious two different sheet materials, each with different thicknesses and flexibilities and with a blind hole in one of the sheets or three different sheets with two cavities.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. patents 3,854,383 are drawn to introducers for catheters. And U.S. patent 4,710,169 is drawn to a urinary catheter with a collapsible urethral tube.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Linh Truong whose telephone number is 703-605-4974.

The examiner can normally be reached on Mondays to Fridays from 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on 703-305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Linh Truong

L.T.


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